SE

S.3 Biodefense Provisions

Summary

Last year, Congress passed and President George W. Bush signed into law the Project BioShield Act of 2003 (Public Law 108-276). Building on the BioShield Act, the S.3 biodefense provisions take the necessary steps to better protect and strengthen our domestic public health infrastructure. Specifically, S.3 eliminates barriers to encouraging and developing the tools needed to protect the nation. It improves the availability and accessibility of vaccines. Additionally, it strengthens our capacity and coordination, so that we respond efficiently in the event of a public health emergency.

Section-by-Section Summary

TITLE I – Biopreparedness Act of 2005

Subtitle A – Product Development

Chapter 1 – Partnering with the Private Sector

- Expands the definition of "qualified countermeasures" to include detection technologies and research tools. Importantly, this provision will help capture additional technologies and countermeasures in order to encourage the market in those directions.

- Explores avenues for public/private partnership by requiring the Secretary to study the feasibility and availability of contributions or guarantees from private organizations, international health agencies, and non-governmental organizations to enhance the procurement or development of qualified countermeasures.

- Encourages vaccine and countermeasure production by ensuring full patent restoration for the developed product.

- Promotes additional international collaboration by requiring the Secretary of Health and Human Services to provide an annual report to Congress on the activities, progress, and barriers to implementation of ongoing activities at the Department of Health and Human Services.

- Provides grants to study animal responses to bioterrorism and infectious agents, encouraging the development of additional research tools.

- Improves efficiency during a public health emergency by allowing companies, which are involved in the development of priority

countermeasures, to better coordinate the development, manufacture, distribution, purchase or sale of priority countermeasures.

Chapter 2 -- Ensuring Regulatory Efficiency

- Establishes an expert commission to conduct a study of the statutes, regulations, guidelines, and compliance, inspection, and enforcement practices and policies that are applicable to countermeasures and vaccines that are in periodic short supply in the United States. The commission is required to submit a report within 6 months containing the results of the study and recommendations to 1) reduce waste, 2) increase efficiency, and 3) ensure rapid availability of safe and effective products.

- Creates an FDA rapid-action team to work with the manufacturer to identify and resolve problems by providing continuous, onsite assistance, in the event that such compliance issues could lead to a significant shortage of a vaccine.

- Requires drug and vaccine manufacturers to promptly forward all communications between it and any foreign regulatory body to the Food and Drug Administration (FDA) if the content of such communications may impact the introduction of a drug or vaccine into the United States.

- Ensures fast track reviews for second generation vaccines and countermeasures.

- Provides for federal pre-emption of any State or local regulatory requirements that alter federal statutory or regulatory requirements for the safety, efficacy, labeling, or advertising of drugs and biological products, thereby impeding access to FDA-approved products.

Chapter 3 – Encouraging Vaccine Production Capacity

- Encourages the construction and renovation of vaccine and countermeasure manufacturing facilities as well as increased vaccine and countermeasure research and development by offering tax-based incentives.

- Promotes a robust vaccine stockpile program and ensures the completion of future stockpile requests by permitting manufacturers to realize revenues for fulfilled stockpile orders.

Subtitle B – Litigation Reform

Chapter 1 – Safety Expansion for Countermeasures and Products Protecting Against Pandemics

- Encourages the development of countermeasures and products protecting against pandemics by expanding Safety Act coverage to those who develop, distribute, prescribe, and administer these countermeasures in an emergency.

Chapter 2 – Vaccine Injury Compensation Program

- Highlights shortcomings in the Vaccine Injury Compensation Program that have contributed to a decline in the availability of vaccines generally in the United States and a decline in the number of manufacturers able to supply vaccines. Requires the Secretary and the Attorney General of the United States to make recommendations to Congress regarding necessary modifications to the Vaccine Injury Compensation Program and federal rules regarding litigation involving vaccines.

Subtitle C – Public Health Preparedness

Chapter 1 – Capacity to Respond

- Establishes the Pandemic Influenza Preparedness and Response Plan which includes developing research to improve influenza vaccines, enhancing public awareness, improved international and state surveillance capacity and the ability to direct vaccines and countermeasure to where they are most needed.

- Authorizes a real time electronic IT structure for disease reporting to improve and enhance surveillance of infectious diseases and potential bioterror attacks. Establishes a "Biointelligence Unit" at CDC to analyze the real time data. Authorizes TA, Coordination and Communication. Broadens disease surveillance to include detection and response to food-borne illnesses.

- Requires the Department to provide reports, budgets and applications to an outside evaluator for monitoring and evaluation purposes.

- Enhances public health surveillance by requiring nonimmigrant health screening for long-term visa applicants.

- Permits the inspection, screening, and quarantining of live animals entering the United States for commercial or other purposes to protect domestic animal and human populations from diseases carried by imported live animals.

- Provides authority to procure aircraft for Centers for Disease Control and Prevention (CDC) to enable them to respond to a public health emergency.

Chapter 2 – Public Health Workforce

- Expands the recruitment and retention of public health workers at the federal, state, and local levels by offering loan repayments in return for service in the FDA, NIH, CDC or other public health agency.

Chapter 3 – Preparedness Updates

- Requires the General Accounting Office to submit a report regarding biopreparedness to Congress no later than one year following enactment. This report includes a review and assessment of 1) the strategic national stockpile, 2) current state and local disease monitoring and control activities, 3) the health care community's ability to respond to a public health emergency, 4) supply chain management, 5) ongoing federal preparedness activities, 6) progress of state preparedness plans, and 7) implementation of the National Preparedness Plan, including preparedness goals and measures.

- Highlights that in order to effectively combat bioterrorism and prevent the spread of deadly infectious disease, the United States should enhance cooperation and its activities globally.